K061301

510(k) Summary
for
Copan Liquid Amies Elution Swab (ESwab)
Collection and Transport System

1. SPONSOR

JUN 23 2006

Copan Diagnostics Inc.
2175 Sampson Avenue, Suite 124
Corona, CA 92879

Contact Person: Norman Sharples
Telephone: 800-216-4016

Date Prepared: May 8, 2006

2. DEVICE NAME

Proprietary Name: Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System
Common/Usual Name: Transport Culture Medium Devices
Classification Name: Transport Culture Medium Devices

3. PREDICATE DEVICES

- BBL™ Port-A-Cul™ Specimen Collection and Transport Products (Port-A-Cul™)
  Becton, Dickinson and Company
  K854986
- Copan Venturi Transystem® Amies Medium Without Charcoal (Venturi Transystem®)
  Copan Diagnostics Inc.
  K972448 and K946287

4. DEVICE DESCRIPTION

Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System is supplied in a collection kit format. Each collection kit consists of a sterile package containing a plastic screw-cap tube with conical shaped bottom filled with 1 ml of Liquid Amies transport medium and a small sterile peel pouch containing one of two sizes of a specimen collection swab that has a tip flocked with soft nylon fiber.

The Liquid Amies transport medium is a maintenance medium comprising inorganic phosphate buffer, calcium and magnesium salts and sodium chloride with a reduced environment due to the presence of sodium thioglycollate. The medium is designed to maintain the viability of aerobic bacteria, anaerobic bacteria and fastidious bacteria such as *Neisseria gonorrhoeae* during transit to the testing laboratory.

The nylon flocked specimen collection swabs provided with the Copan ESwab Collection and Transport System have a solid plastic shaft with a molded breakpoint site. Copan ESwab Collection and Transport System kits are available with two different size nylon flocked swab options to facilitate the collection of specimens from various sites on a patient.

5. INTENDED USE

Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System is intended for the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the collection site to the testing laboratory. In the laboratory, ESwab specimens are processed using standard clinical laboratory operating procedures for bacterial culture.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Copan ESwab products are substantially equivalent to the predicate transport culture medium devices. The Copan ESwab products and the predicate devices are similar in intended use and overall function.

The proposed and predicate devices are single-use products intended for the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria. Both the Copan ESwab and the predicate devices are offered in collection kit formats with specimen collection swab options.

7. PERFORMANCE TESTING

Studies were conducted to evaluate the performance characteristics of the Copan ESwab System components as well as the complete ESwab collection kit formats. Recovery studies were performed using the Copan ESwab and the predicate devices to determine the ability of the products to maintain viability of various strains of aerobic, anaerobic and fastidious bacteria during storage and use. Stability testing was performed on aged Copan ESwab products to support the 15-month expiration date.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 23 2006

Copan Diagnostics, Inc.
c/o Ms. Cynthia A. Sinclair, RAC
Principal Consultant, Regulatory Services
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: k061301
Trade/Device Name: Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System
Regulation Number: 21 CFR§866.2900
Regulation Name: Microbiological specimen collection and transport device
Regulatory Class: Class I
Product Code: JTW. JTX
Dated: May 8, 2006
Received: May 10, 2006

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA). it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061301

Device Name: Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System

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Prescription Use X AND/OR Over-the-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K061301